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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,304	08/25/2000	Airton Monza da Silveira	1369-00	6411

22469 7590 02/12/2004

SCHNADER HARRISON SEGAL & LEWIS, LLP  
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PHILADELPHIA, PA 19103

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/648,304

Applicant(s)

SILVEIRA ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**First Office Action on the Merits of a RCE**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 7, 2003 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2 and 4-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite, “the cyclic oligosaccharide molecules are localized on the surface of the nanoparticles”. The present specification lacks description of said limitation and, thus, the specification does not convey to the skilled artisan that applicant, at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 103***

**5. The rejection of claims 1, 2 and 4-13 under 35 USC 103(a) over Chen et al. (US Patent 5,932,248) in view of Trinh (US Patent 5,246,611) is maintained.**

Applicant argues the combination of the above-cited references does not make obvious the claimed invention wherein the active ingredient is largely contained in a nanoparticle matrix network and the cyclic oligosaccharide molecules are localized on the surface of the nanoparticles. Applicant’s argument was considered but not persuasive for the following reason.

First, the examiner notes that applicant’s argument as indicated above was considered and addressed by the previous Office Action (see page 4 of the previous Office Action).

As stated in the previous Office Action, the instant specification discloses a drug-cyclodextrin complex (see page 7, lines 6-15; page 8, lines 6-18; page 11, lines 12-16). According to the present specification, (a) “[t]he nanoparticles of the invention are based on the ability of a molecule of an active ingredient to combine itself with one or more cyclodextrin molecules...” (see page 7, lines 6-15 of the present specification); (b) “complexation of the active ingredient during preparation of the nanoparticles of the

Art Unit: 1616

invention makes it possible to protect the active ingredient against chemical reactions that are necessary for the formation of the particle.” (see page 8, lines 7-9 of the present specification) and (c) “it is observed that poly(alkylcyanoacrylate) stabilizes the complex made up of the active ingredient and the compound able to complex the active ingredient” (see page 11, lines 15-16 of the present specification). Based on the disclosure of a drug-cyclodextrin by the present specification, it is the examiner’s position that the combination of references suggests the limitations of the instant claims.

For this reason and those given in previous Office Actions, the rejection of claims 1, 2 and 4-13 under 35 USC 103(a) over Chen et al. (US Patent 5,932,248) in view of Trinh (US Patent 5,246,611) is maintained.

**6. The rejection of claims 1, 2 and 4-26 under 35 USC 103(a) over Ramtoola (US Patent 5,641,515) in view of Trinh (US Patent 5,246,611) is maintained.**

Applicant’s argument and the examiner’s response are as discussed above in #5.

For this reason and those given in previous Office Actions, the rejection of claims 1, 2 and 4-26 under 35 USC 103(a) over Ramtoola (US Patent 5,641,515) in view of Trinh (US Patent 5,246,611) is maintained.

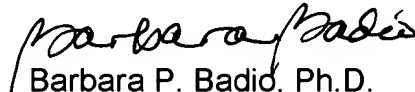
***Telephone Inquiry***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
February 11, 2004